

Ab interno canaloplasty for open-angle glaucoma

Interventional procedures guidance

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www.nice.org.uk/guidance/ipg745

Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the [Yellow Card Scheme](#).

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with

those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

1 Recommendations

- 1.1 Evidence on the safety of ab interno canaloplasty for open-angle glaucoma shows no major safety concerns. Evidence on the efficacy is limited in quality and quantity, particularly in the long term. Therefore, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research. Find out what special arrangements mean on the NICE interventional procedures guidance page.
- 1.2 Clinicians wanting to do ab interno canaloplasty for open-angle glaucoma should:
- Inform the clinical governance leads in their healthcare organisation.
 - Give people (and their families and carers, as appropriate) clear information to support shared decision making, including NICE's information for the public.
 - Ensure that people (and their families and carers, as appropriate) understand the procedure's safety and efficacy, and any uncertainties about these.
 - Audit and review clinical outcomes of everyone having the procedure. The main efficacy and safety outcomes identified in this guidance can be entered into NICE's interventional procedures outcomes audit tool (for use at local discretion).
 - Enter details about everyone having ab interno canaloplasty for open-angle glaucoma onto a suitable registry and review local clinical outcomes.
 - Discuss the outcomes of the procedure during their annual appraisal to reflect, learn and improve.
- 1.3 Healthcare organisations should:

- Ensure systems are in place that support clinicians to collect and report data on outcomes and safety for everyone having this procedure.
 - Regularly review data on outcomes and safety for this procedure.
- 1.4 Patient selection and treatment should be done by glaucoma specialists with training and experience in the technique.
- 1.5 Report any problems with a medical device using the [Medicines and Healthcare products Regulatory Agency's Yellow Card Scheme](#).
- 1.6 Further research should report:
- details of patient selection, including concurrent procedures, severity of glaucoma and concomitant therapy
 - long-term efficacy and safety outcomes.

2 The condition, current treatments and procedure

The condition

- 2.1 Glaucoma is usually a chronic condition that is typically associated with raised intraocular pressure (IOP). The most common type of glaucoma in the UK is primary open-angle glaucoma. It leads to progressive damage to the optic nerve. Early stages are usually asymptomatic. But, as the condition progresses, it can cause visual impairment and, if untreated, blindness.
- 2.2 In the healthy eye, aqueous humor drains through the trabecular meshwork (into Schlemm's canal) and through the uveoscleral outflow pathway. In glaucoma, this drainage becomes impaired, either from resistance in the trabecular meshwork pathway (primary open-angle glaucoma) or from obstruction by the iris (primary closed-angle glaucoma).

Current treatments

- 2.3 Treatment usually involves eye drops containing medicines that either reduce the production of aqueous humor or increase its drainage. Surgical procedures such as trabeculectomy, deep sclerectomy, trabeculotomy, stenting, canaloplasty or laser trabeculoplasty may be used.

The procedure

- 2.4 Ab interno canaloplasty aims to reduce IOP by improving the drainage of aqueous fluid from the eye in people with open-angle glaucoma. It is usually done under local anaesthesia, but general anaesthesia can be used. Unlike traditional (ab externo) canaloplasty, which is done by cutting through the conjunctiva and sclera, ab interno canaloplasty uses an internal approach through a clear corneal or limbal incision. A microcatheter is introduced into the canal through a small opening in the trabecular meshwork and advanced around its entire circumference. As the catheter tip is withdrawn, viscoelastic fluid is injected into the canal to dilate it. The microcatheter is then removed. The viscoelastic fluid disperses down the collector channels of the eye within 2 to 3 days. The aim is to permanently dilate the canal to allow increased drainage of aqueous humor from the eye and thereby lower IOP. Some devices allow canaloplasty to be done sequentially with trabeculotomy as part of a single operation. Canaloplasty is often done concurrently with phacoemulsification (cataract surgery).

3 Committee considerations

The evidence

- 3.1 NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 8 sources, which was discussed by the committee. The evidence included 7 before-and-after studies. It is presented in the [summary of key evidence section in the interventional procedures overview](#). Other relevant

literature is in the appendix of the overview.

- 3.2 The professional experts and the committee considered the key efficacy outcomes to be: reduction in intraocular pressure (IOP), reduction in glaucoma medicine use, need for further IOP-controlling surgery, preservation of peripheral vision, and patient-reported outcomes, including quality of life.
- 3.3 The professional experts and the committee considered the key safety outcomes to be: pain, bleeding within the eye, infection, loss of vision, hypotony and need for further surgery for complications.
- 3.4 Three commentaries from people who have had this procedure were discussed by the committee.

Committee comments

- 3.5 Glaucoma is a common chronic condition. This underpinned the committee's recommendation on collecting and reporting further data on outcomes and safety, particularly in the long term.
- 3.6 The committee was informed that this procedure is for people with mild-to-moderate glaucoma.
- 3.7 More than 1 device is available for this procedure.
- 3.8 The committee was informed that people with glaucoma need lifelong follow up, and some may need to continue using glaucoma medicine after the procedure.

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Endorsing organisation

This guidance has been endorsed by [Healthcare Improvement Scotland](#).